UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/473,789	06/07/95	CURTISS R	MEGAN-100-21

HM12/0725

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EXAMINER	
RYAN, V	

ART UNIT	PAPER NUMBER
1645	34

DATE MAILED: 07/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/473,789	Curtiss
Examiner	**Group Art Unit**
V. Ryan	1641

☒ Responsive to communication(s) filed on *Apr 10, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-16, 20-32, 35-38, and 41-45* is/are pending in the application.

Of the above, claim(s) *5-7, 15, 21, 22, 25, 26, 36, and 38* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4, 8-14, 16, 20, 23, 24, 27-32, 35, 37, and 41-45* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges receipt of the amendment filed April 10, 2000.

In this application:

Claims 1, 23, 27, 30 and 41-43 were amended.

Claims 1-16, 20-32, 35-38 and 41-45 are now pending.

Claims 5-7, 15, 21, 22, 25, 26, 36 and 38 are withdrawn from consideration by the Examiner.

Claims 1-4, 8-14, 16, 20, 23, 24, 27-32, 35, 37 and 41-44 are now under examination.

Response to Amendment

(1) The rejection of claims 1-4, 8-14, 16, 20, 23, 24, 27-32, 35, 37 and 41-44 under 35 U.S.C. 112, first paragraph is withdrawn.

(2) The rejection of claims 1-4, 8-14, 16, 20, 23, 24, 27-32, 35, 37 and 41-44 under 35 U.S.C. 112, second paragraph is withdrawn.

The following are new grounds of rejections:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1-4, 8-14, 16, 20, 23, 24, 27-32, 35, 37 and 41-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 8, 11, 15-23, 31, 32, 35, 36, 39-41 and 44-52 of U.S. Patent No. 08/761,769. Although the conflicting claims are not identical, they are not patentably distinct from each other because .

Claim Rejections

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection was previously set forth in the Office Action of November 13, 1998 (Paper #25).

Claims 1-4, 8-14, 20, 23, 24, 27-29 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Molin et al.

Molin et al (US Patent #5,702,916) disclose a biological containment system in which a cell containing a recombinant DNA molecule expresses a cell-killing function in certain environmental conditions. The cell killing function can be regulated by means of a promoter. (See especially Abstract; column 2, lines 30-51; column 3; column 6, lines 59-67; column 7, lines 1-22).

In addition, Molin et al disclose that the DNA can be a bacterial plasmid, or a bacterial chromosome. (See especially column 5, first paragraph).

Molin et al also disclose promoters such as λPR or PL, controlled by temperature-sensitive regulating factors or lac, ara or deo promoters which are activated by the presence of lactose, arabinose and pyrimidine nucleosides, respectively. (See especially column 8).

Moreover, Molin et al disclose that the hok gene can be used since it expresses a cell-killing function when insufficient concentrations of the inhibitory sok RNA are present. (See especially column 10, lines 24-49; column 41, lines 40-64).

It is noted that claims 27-29 are directed to a method of making a cell strain. However, the claims contain no limitations

that further distinguish the method of making the cell from the cell.

The term "vaccine" is viewed as an intended use for the cell as the claims do not contain any further limitations that distinguish the composition from the prior art.

Therefore, the prior art disclosure is viewed as anticipating the claims.

In the response to the Office Action of November 13, 1998 (Paper #25), Applicant asserts that the reference does not express the lethal gene at any given time. According to Table 1 of the response, the only difference between the cited publication and the claimed invention is that the hok gene, in the cited publication, is not expressed at either 42 or 30 degrees. Applicant further asserts that the sok gene described by Molin et al does not correspond to any inactivated native gene of the cell.

However, Molin et al disclose a biological containment system wherein the cell killing function can be regulated so that the cell is killed under certain conditions. (See especially column 5, lines 10-36; column 12, lines 42-63; column 16, lines 40-67; column 17, lines 1-12). Contrary to Applicant's

assertions, the death of the cell occurs due to the expression of the gene encoding the cell killing function as a result of pre-determined environmental conditions. (See especially column 6, lines 24-64; column 18, lines 36-65). The sok gene is considered essential to the cell because it suppresses the lethal effects of the hok gene, thereby preventing cell death.

Claims 1, 4, 10-12, 20, 27, 41-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Curtiss, III.

Curtiss, III ("The Release of Genetically-engineered Micro-organisms." Proceedings of the First International Conference on the Release of Genetically-engineered Micro-organisms. (Sussman et al, eds.), Academic Press, 1988. Pages 7-19) disclose genetically-engineered micro-organisms which contain the hok gene as a lethal gene, and the asd+ gene as an essential gene. The hok gene can be fused to a promoter to regulate expression of the lethal hok gene (See especially page 12).

Therefore, the reference is viewed as anticipating the claims.

The Group and/or Art Unit location of your application in the Patent and Trademark Office may have changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703)305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Papers related to this application may be submitted to the Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1645 is (703)308-4242.

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July 2000
Ryan/vr

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